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| 09/927,884 | 08/10/2001 | Gary Van Nest | 377882001720 | 5141 |

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| EXAMINER |
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NAVARRO, ALBERT MARK

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,884

Applicant(s)

VAN NEST ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 14, 16-63, 69 and 71-80 is/are pending in the application.
- 4a) Of the above claim(s) 29-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 14, 16-23, 25-29, 56-63, 69 and 71-80 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/2/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2004 has been entered.

Accordingly, claims 1-8, 14, 16-63, 69, 71-80 are pending in the instant application, of which claims 30-55 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-8, 14, 16-23, 25-29, 56-63, 69, and 71-80 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained.

Applicants are asserting that the claimed invention is directed to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a nonbiodegradable microcarrier. Applicants further assert that

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in claim 20, the polynucleotide in the complex is 7 nucleotides in total length, including the dinucleotide sequence 5'-CG-3'. Applicants have further amended the claims to recite that the polynucleotide is less than about 200 nucleotides in length and comprises a specific 7 nucleotide sequence. Applicants point towards pages 22-25 which identifies a discrete number of members of the claimed genus, approximately 100 in total, as fulfilling the written description requirement.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that in claim 20, the polynucleotide in the complex is 7 nucleotides in total length, including the dinucleotide sequence 5'-CG-3'. However, this broad genus claims remains unsupported by the written description requirement. Van Uden et al (Journal of Allergy and Clinical Immunology Vol. 104, No. 5, pp 902-910, November 1999) set forth that "Even after intensive attempts to precisely define the DNA sequence structure required for immune stimulation, this most fundamental aspect of ISS is only partially understood." (See page 903). Furthermore, Fearon et al (Eur. J. Immunol. Vol. 33, pp 2114-2122, 2003) set forth that "flanking sequences" of ISS molecules can have "confounding effects." (See page 2115). Accordingly, without guidance towards a detailed structure of the ISS molecule and additionally the flanking sequences (i.e., consisting of) which can have a profound impact on the activity of this molecule, one of skill in the art would not be able to readily identify members of the claimed genus.

Claims 1-8, 14, 16-23, 25-29, 56-63, 69, and 71-80 recite a immunomodulatory polynucleotide/microcarrier comprising an immunostimulatory sequence (ISS) linked to a nonbiodegradable microcarrier (MC), wherein the ISS comprises a sequence selected from the group consisting of TCGAAAA, TCGCCCC, TCGGGGG, TCGTTTT, and TCGTCGX, and wherein the polynucleotide is less than about 200 nucleotides in length.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, an "ISS oligonucleotide sequence identified in the claims" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

2. The rejection of claims 20 and 26 under 35 U.S.C. 102(b) as being anticipated by Uhlen is withdrawn in view of Applicants arguments.

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The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

3. Claims 1-8, 14, 16-23, 25-29, 56-63, 69, and 71-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for IMP/MC complexes wherein the ISS **consists** of TCGAAAA, TCGCCCC, TCGGGGG, TCGTTTT, or TCGTCGX, does not reasonably provide enablement for IMP/MC complexes wherein the ISS **comprises** TCGAAAA, TCGCCCC, TCGGGGG, TCGTTTT, or TCGTCGX. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir. 1999).

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Van Uden et al (Journal of Allergy and Clinical Immunology Vol. 104, No. 5, pp 902-910, November 1999) set forth that "Even after intensive attempts to precisely define the DNA sequence structure required for immune stimulation, this most fundamental aspect of ISS is only partially understood." (See page 903).

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Turning towards the Wands Analysis, Van Uden et al have addressed Factors 1, 4, 5, and 7 in showing that the predictability of the invention is highly complex given that "intensive attempts" have been made to define the structure of DNA required for immune stimulation, and has resulted in only limited success. Furthermore, Fearson et al also addresses Factors 1, 4, 5 and 7 by showing that the flanking sequences (upstream and downstream) of an ISS molecule can have confounding effects on the activity of the molecule.

Given the unpredictable nature of the invention, the difficulty in identifying ISS sequences by those in the prior art, and the limited guidance contained in the specification identifying flanking regions, one of skill in the art would be forced into excessive experimentation to practice the broadly claimed invention.

Double Patenting

4. Claim 25 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 21. When two claims in an application are duplicates or else are so close in

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content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 24 is objected to for depending upon a rejected base claim, however claim 24 is free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
December 23, 2004